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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,664	08/15/2002	Mou Tuan Huang	11592-006-999	2837
20583	7590	04/20/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

CS

<b>Office Action Summary</b>	<b>Application No.</b> 10/088,664	<b>Applicant(s)</b> HUANG ET AL.	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-24,26-28,30-32 and 34-51 is/are pending in the application.
- 4a) Of the above claim(s) 38-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24,26-28,30-32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>27/1/2006</u> | 6) <input type="checkbox"/> Other: _____  |

1/27/2006

## **DETAILED ACTION**

1. Applicants' response filed 27 January 2006 to Office Action mailed 26 October 2005 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. To facilitate processing of papers at the USPTO, Examiner recommends that the Application Serial Number and Attorney's Docket Number be inserted in the header on every page of each and every paper filed in all future communications with this office.
3. In view of applicants' amendment and arguments filed 27 January 2006, Examiner herewith withdraws the following rejections in Office Action mailed 26 October 2005.
  - rejection to Claims 22-37 under 35 U.S.C. § 112, second paragraph.

## **CLAIMS STATUS**

3. Claims 1-21, 25, 29 and 33 have been cancelled.
4. Claims 38-51 are added.
5. Claims 22-24 and 37 have been amended.
6. Claims 22-24, 26-28, 30-32, 34-37 and 38-51 are pending and are examined on merits.
7. Newly presented claims 38-51 are drawn to a method to inhibit growth of colon cancer in a human, rather than to treat colon cancer that already exists, and therefore the invention claimed in those claims is drawn to a method different in scope than those for the invention currently under prosecution. Said method and the method currently under prosecution are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, steps, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01).
8. Accordingly, newly presented claims 38-51 are withdrawn from further consideration.
9. Claims 22-24, 26-28, 30-32, 34-37 are examined on merits.

## **Information Disclosure Statement**

10. Applicants' Supplemental Information Disclosure Statement (i.e., IDS) filed 27 January 2006 has been made of record and references designated as C47 cited therein has been considered.

## **Priority**

11. In response to the acknowledgement granted for the claimed priority date of 09/21/1999, which is the filing date for U.S. Provisional application No. 60/155, 018 under 35 U.S.C. §119 (e), applicants present the same argument that they presented with the originally filed application and further argue that the application under prosecution is a National Stage application of PCT/US00/25733 and thus has the same specification as said PCT application. Applicants' arguments are fully and carefully considered but are not persuasive for the reasons of record at page 2, item 5 of the Office Action mailed November 17, 2003. Applicants are further reminded that the application currently under prosecution is an RCE of the Original Application 10/088,664. Application 10/088, 664 was a National Stage submission of PCT/US00/25733 under 35 U.S.C. §371. The current RCE is prosecuted under 37 C.F.R. § 1.1 14.

## **Double Patenting**

12. Claims 22-24, 26-28, 30-32, 34-37 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39, 43, 63 and 71-72 of Co-pending U.S. Patent Application No. 09/992,860. Although, conflicting claims are not identical, they are not patentably distinct from each other because claims 39, 43, 63 and 71-72 referenced U.S. Patent Application are drawn to a composition comprising the same ingredients and essentially the same steps to obtain a the method to treat/prevent colon cancer as claimed in the recited claims of instant application.

In response filed 27 January 2006, Applicants request that this obviousness type double patenting rejection be held in abeyance. In response to this final office action, applicants are required to submit a terminal disclosure as stated under item 12 of the Double Patenting rejection in Office Action mailed 26 October 2005.

## **Claim Rejections - 35 U.S.C. § 112**

13. Claims 23-24, 26-28, 30-32, 34-37 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for a method to treat colon cancer via administering a composition

comprising a mixture containing all the 14 components of orange peel extract (Specification, Page 4, Line 27 to Page 7, Line 21) or a mixture of tangeritin and nobeletin (Specification page, 7, Line 22 to Page 9, Line 7) or only resveratrol (See Page 12, Line 4 to Page 14, Line 19), does not reasonably provide enablement for a method to prevent colon cancer via instantly claimed method of administering the instantly claimed pharmaceutical composition comprising orange peel extract/ alleged all 14 components of orange peel extract in mixture with extracts of other plants, other phytochemicals or with resveratrol as claimed.

In response to this rejection, reciting examples from specification applicants argue that the claims under prosecution are enabled for the claimed invention of prevention. Applicants arguments are fully and carefully considered but are not persuasive because in applicants' cited example the reduction in colon cancer subsequent to administering applicants claimed composition according to the claimed method is only 48%. Prevention means complete absence which the applicants method/specification does not demonstrate.

10. 14. Upon resolution of the above-stated issues, further searching and/or consideration may be required.

### **CONCLUSION**

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. No Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1655  
(571) 272-0923

April 17, 2006

  
**CHRISTOPHER R. TATE**  
**PRIMARY EXAMINER**